CLAIMS

Claims 1 – 58 (cancelled)

Claim 59. (currently amended) A method comprising administering a therapeutically effective amount of a composition comprising pharmaceutically acceptable carrier material and anti-HIV ingredients, wherein the anti-HIV ingredients in the composition consist of [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine) to a patient in need of antiviral therapy consisting of anti-HIV therapy, and wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the composition in relation to carrier material is about 5% to about 95% of the total composition weight:weight, exclusive of coating).

Claim 60. (canceled)

Claim 61. (previously presented) The method of claim 59 wherein the composition comprises about 300 mg of tenofovir disoproxil fumarate and about 200 mg of emtricitabine.

Claim 62. (canceled)

Claim 63. (original) The method of claim 59 wherein tenofovir disoproxil fumarate and emtricitabine are present in a tablet.

Claim 64. (original) The method of claim 63 wherein tenofovir disoproxil fumarate and emtricitabine are present in an amount of 300 mg and 200 mg respectively.

Claim 65. (canceled)

Claim 66. (currently amended) The method of claim ~~62~~ 59 wherein the weight ratio of the total of tenofovir disoproxil fumarate and emtricitabine in the composition in relation to ingredients other than tenofovir disoproxil fumarate and emtricitabine is 50:50 (excluding coating).

Claim 67. (original) The method of claim 66 wherein the composition comprises in weight percent (excluding coating) tenofovir disoproxil fumarate 30, emtricitabine 20, pregelatinized starch 5, croscarmellose sodium 6, lactose monohydrate 8, microcrystalline cellulose 30, magnesium stearate 1.

Claim 68.-69. (canceled)

Claim 70. (original) The method according to claim 59 wherein the composition further comprises a pharmaceutically acceptable glidant.

Claim 71. (original) The method according to claim 70 wherein the glidant is selected from silicon dioxide, powdered cellulose, microcrystalline cellulose, metallic stearates, sodium aluminosilicate, sodium benzoate, calcium carbonate, calcium silicate, corn starch, magnesium carbonate, asbestos free talc, stearowet C, starch, starch 1500, magnesium lauryl sulfate, magnesium oxide, and formulations thereof.

Claim 72. (original) The method according to claim 71 wherein the metallic stearates are selected from calcium stearate, magnesium stearate, zinc stearate, and formulations thereof.

Claim 73. (currently amended) A pharmaceutical formulation comprising carrier material and anti-HIV ingredients, wherein the anti-HIV ingredients in the formulation consist of [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine), and wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the formulation in relation to carrier material (weight:weight, excluding coating) is about 5% to about 95% of the total composition.

Claim 74. (canceled)

Claim 75. (original) The pharmaceutical formulation according to claim 74 wherein the pharmaceutically acceptable carriers or excipients are selected from pregelatinized starch, croscarmellose sodium, povidone, lactose monohydrate, microcrystalline cellulose, and magnesium stearate, and formulations thereof.

Claim 76. (canceled)

Claim 77. (currently amended) The pharmaceutical formulation according to claim ~~76~~ 74 wherein the weight ratio of tenofovir disoproxil fumarate and entricitabine together[[:]] to the total weight of ~~carrier and excipient in~~ the formulation (excluding

coating) is 500:1000, 400:900, 325:825, 225:725, 200:700, 500:700, 500:670, 500:763, 500:2840 or 500:2270.

Claim 78. (original) The pharmaceutical formulation according to claim 77 wherein the weight ratio (excluding coating) is 0.50, 0.44, 0.39, 0.31, 0.29, 0.71, 0.75, 0.65, 0.18 or 0.22.

Claim 79. (currently amended) The pharmaceutical formulation according to claim ~~76~~ 74 wherein the weight ratio of tenofovir disoproxil fumarate and emtricitabine together~~: total carrier and excipient in~~ to the total weight of the formulation (excluding coating) is from 0.18 to 0.75.

Claim 80. (original) The pharmaceutical formulation according to claim 73 in pharmaceutical dosage form.

Claim 81. (original. The pharmaceutical formulation according to claim 80 wherein the pharmaceutical dosage form is a tablet.

Claim 82. (original) The pharmaceutical formulation according to claim 73 wherein tenofovir disoproxil fumarate and emtricitabine are present in a ratio of about 300:200 by weight.

Claim 83. (currently amended) The pharmaceutical formulation according to claim 82 wherein the amounts of tenofovir disoproxil fumarate and emtricitabine are ~~30mg~~ 300mg and 200mg respectively.

Claim 84. (original) The pharmaceutical formulation according to claim 73 suitable for oral administration.

Claim 85. (original) The pharmaceutical formulation according to claim 84 wherein the pharmaceutical dosage form is a capsule.

Claim 86. (original) The pharmaceutical formulation according to claim 73 suitable for administration once per day to an infected human.

Claim 87. (currently amended) A patient pack comprising (a) at least one coformulated pharmaceutical formulation comprising pharmaceutically acceptable carrier material and anti-HIV active ingredients, wherein the anti-HIV active ingredients in the anti-HIV formulation consist of [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine), and wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the composition in relation to carrier material is about 5% to about 95% of the total composition (weight:weight, excluding coating), and (b) an information insert containing directions for the use of tenofovir disoproxil fumarate and emtricitabine in formulation for the treatment of a patient in need of anti-HIV treatment.

Claim 88. (previously presented). The patient pack according to claim 87 wherein the pharmaceutical dosage form is a tablet, caplet, or capsule wherein the amounts of tenofovir disoproxil fumarate of emtricitabine are 300mg and 200mg respectively.

Claim 89. – 95. (canceled)

Claim 96. (currently amended) An oral pharmaceutical dosage form wherein the anti-HIV active ingredients in the dosage ~~from~~ form consist of tenofovir disoproxil fumarate, emtricitabine and efavirenz ~~Sustiva~~.

Claim 97. (canceled)

Claim 98. (currently amended) A tablet comprising pharmaceutically acceptable carrier material and anti-HIV ingredients, wherein the anti-HIV ingredients in the tablet consist of 300 mg of tenofovir disoproxil fumarate, and 200 mg of emtricitabine~~, together with~~ wherein the carrier[[s]] ~~and/or excipients~~ material is sufficient to produce less than 5% acid degradation of tenofovir disoproxil fumarate or emtricitabine after six months storage with desiccant at 40°C/75% ~~25%~~ relative humidity.

Claim 99. (currently amended) An oral dosage form wherein the anti-HIV ingredients in the dosage form consist of efavirenz ~~Sustiva~~, 300 mg tenofovir disoproxil fumarate and 200 mg of emtricitabine, together with pharmaceutically acceptable carriers and/or excipients.

Claim 100. (currently amended) A method comprising administering to a patient in need of anti-HIV therapy a therapeutically effective amount of a composition comprising pharmaceutical carrier material and anti-HIV ingredients, wherein the anti-HIV active ingredients in the composition consist of efavirenz ~~Sustiva~~, [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl}-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine)~~ to a patient in need of anti-HIV therapy~~, and wherein the amount of the total tenofovir disoproxil

fumarate and emtricitabine in the composition in relation to carrier material is about 5% to about 95% of the total composition (weight:weight, exclusive of coating).

Claim 101. (previously presented)The method of claim 100 wherein the composition comprises about 300 mg of tenofovir disoproxil fumarate and about 200 mg of emtricitabine.

Claim 102. (canceled)

Claim 103. (previously presented)The method of claim 100 wherein the composition is a tablet.

Claim 104. (previously presented)The method of claim 103 wherein tenofovir disoproxil fumarate and emtricitabine are present in an amount of 300 mg and 200 mg respectively.

Claim 105. (previously presented)The method of claim 102 wherein the weight ratio of the total of tenofovir disoproxil fumarate and emtricitabine in the composition in relation to ingredients other than tenofovir disoproxil fumarate and emtricitabine is 50:50 (excluding coating).

Claim 106. (previously presented)The method according to claim 100 wherein the composition further comprises a pharmaceutically acceptable glidant.

Claim 107. (previously presented)The method according to claim 106 wherein the glidant is selected from silicon dioxide, powdered cellulose, microcrystalline cellulose, metallic stearates, sodium aluminosilicate, sodium benzoate, calcium carbonate, calcium silicate, corn starch, magnesium carbonate, asbestos free talc, stearowet C, starch, starch 1500, magnesium lauryl sulfate, magnesium oxide, and formulations thereof.

Claim 108. (previously presented)The method according to claim 107 wherein the metallic stearates are selected from calcium stearate, magnesium stearate, zinc stearate, and formulations thereof.

Claim 109. (currently amended) A pharmaceutical formulation comprising pharmaceutically acceptable carrier material and anti-HIV ingredients, wherein the anti-HIV active ingredients in the formulation consist of efavirenz ~~Sustiva~~, [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and (2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine), and wherein the amount of the total tenofovir disoproxil fumarate and emtricitabine in the formulation in relation to carrier material (weight:weight, excluding coating) is about 5% to about 95%.

Claim 110. (canceled)

Claim 111. (previously presented)The pharmaceutical formulation according to claim 110 wherein the pharmaceutically acceptable carriers or excipients are selected from pregelatinized starch, croscarmellose sodium, povidone, lactose monohydrate, microcrystalline cellulose, and magnesium stearate, and formulations thereof.

Claim 112. (canceled)

Claim 113. (currently amended) The pharmaceutical formulation according to claim 112 wherein the weight ratio of tenofovir disoproxil fumarate and emtricitabine together[[:]] to the total ~~carrier and excipient in~~ weight of carrier material, tenofovir disproxil fumarate and emtricitabine the formulation (excluding coating) is 500:1000, 400:900, 325:825, 225:725, 200:700, 500:700, 500:670, 500:763, 500:2840 or 500:2270.

Claim 114. (previously presented)The pharmaceutical formulation according to claim 113 wherein the weight ratio (excluding coating) is 0.50, 0.44, 0.39, 0.31, 0.29, 0.71, 0.75, 0.65, 0.18 or 0.22.

Claim 115. (currently amended) The pharmaceutical formulation according to claim 112 wherein the weight ratio of tenofovir disoproxil fumarate and emtricitabine together[[:]] to the total ~~carrier and excipient~~ weight of carrier material tenofovir disoproxil fumarate and emtricitabine in the formulation (excluding coating) is from 0.18 to 0.75.

Claim 116. (previously presented)The pharmaceutical formulation according to claim 109 in pharmaceutical dosage form.

Claim 117. (previously presented)The pharmaceutical formulation according to claim 116 wherein pharmaceutical dosage form is a tablet.

Claim 118. (previously presented)The pharmaceutical formulation according to claim 109 wherein tenofovir disoproxil fumarate and emtricitabine are present in a ratio of about 300:200 by weight.

Claim 119. (previously presented)The pharmaceutical formulation according to claim 118 comprising about 300 mg of tenofovir disoproxil fumarate and about 200 mg of emtricitabine.

Claim 120. (previously presented)The pharmaceutical formulation according to claim 109 suitable for oral administration.

Claim 121. (previously presented)The pharmaceutical formulation according to claim 120 wherein the pharmaceutical dosage form is a capsule.

Claim 122. (previously presented) The pharmaceutical formulation according to claim 109 suitable for administration once per day to an infected human.

Claim 123. (currently amended) A patient pack comprising (a) at least one coformulated anti-HIV pharmaceutical formulation comprising pharmaceutically acceptable carrier material and anti-HIV ingredients, wherein the anti-HIV active ingredients in the formulation consist of Efavirenz ~~Sustiva~~, [2-(6-amino-purin-9-yl)-1-methyl-ethoxymethyl]-phosphonic acid diisopropoxycarbonyloxymethyl ester fumarate (tenofovir disoproxil fumarate) and 2*R*, 5*S*, cis)-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one (emtricitabine), and wherein the amount of the total Tenofovir disoproxil fumarate and emtricitabine in the composition in relation to carrier material is about 5% to about 95% of the total composition (weight:weight, excluding coating), and (b) an information insert containing directions for the use of tenofovir disoproxil fumarate, emtricitabine and efavirenz ~~Sustiva~~ in formulation for the treatment of a patient in need of antiviral treatment.

Claim 124. (previously presented)The patient pack according to claim 123 wherein the pharmaceutical dosage form is a tablet, caplet, or capsule wherein the amounts of tenofovir disoproxil fumarate and emtricitabine are 300mg and 200mg respectively.

Claim 125. (currently amended) A tablet comprising pharmaceutically acceptable carrier material and anti-HIV ingredients, wherein the anti-HIV active ingredients in the tablet consist of efavirenz ~~Sustiva~~, 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine, ~~together with~~ and the carrier[[s]] ~~and/or excipients~~ material is sufficient to produce less than 5% acid degradation of tenofovir disoproxil fumarate or emtricitabine after six months storage with desiccant at 40°C/75% [[25%]] relative humidity.